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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kinh-Luan (Lenny) Dao

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MAYER & WILLIAMS PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

10/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/816,677	Applicant(s) DAO ET AL.	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-13, 15, 17-21 and 23-47 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 12, 13, 15, 20, 21, 24, 25, 27-30, 33-38, 44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' pre-appeal review request filed 07/20/2010.

Claims 1-5, 10-13, 15, 17-21, 23-47 previously presented.

Claims 2-4, 12, 13, 15, 20, 21, 24, 25, 27-30, 33-38 are drawn to nonelected invention. Election was made with traverse in the reply filed on 12/03/2007. Claims 44 and 45 were withdrawn from consideration in the office action mailed 04/09/2009 as being directed to non-elected invention by original presentation.

Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46 and 47 are included in the prosecution.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 47 added by the amendment filed 02/09/2010 introduced new matter as the claim recites "wherein the microparticles are selected from metallic microparticles and ceramic microparticles". Nowhere in the specification had applicant disclosed this limitation. In page 10 paragraph [0040] of the specification applicants disclosed that: "As to composition, **the microparticles can comprise ceramic, metallic and polymeric materials,**". In paragraph [0041] applicants stated that: "Examples of ceramic materials **for use in the microparticles of the present invention can be selected from those comprising one or more of the following: metal.....**". Therefore, no support or disclosure whatsoever regarding "microparticles selected from metallic or ceramic microparticles" as instantly claimed by claim 47. The microparticles can only comprise metallic or ceramic materials.

If applicant contends there is support for this limitation, then applicant is requested to specify the page and line of said support. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harish et al. (WO 02/26162, of record) combined with Alt (US 7,713,297, currently listed on PTO 892).

Applicant Claims

Claim 1 is directed to medical article comprising:

- (a) an adhesive region comprising an adhesive;
- (b) a therapeutic agent, wherein at least a portion of said therapeutic agent is adhered to a surface of said adhesive region; and
- (c) microparticles, at least a portion of which are attached to said surface of said adhesive region, wherein said therapeutic agent and said microparticles are applied to said surface of said adhesive region as separate entities and wherein the microparticles create pockets between them which are occupied by the therapeutic agent and from which the therapeutic agent is released.

Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)

Harish teaches implantable device coated on preselected regions/portions of its outer surface with therapeutic agent (abstract; claims 3 and 18). The device can be a stent. The therapeutic agents are deposited on the surface of the device in the form of dry particles (page 3, 2nd and 3rd full paragraphs; claims 7 and 8). The device is covered by polymeric primer prior to applying the therapeutic particles to adhere the particle to the surface of the stent, i.e. adhesive (page 4, 1st full paragraph; page 13, 3rd full paragraph; page 16, 1st full paragraph). Therapeutic particles can be applied on the surface in combination and include protein, which is a macromolecule, radio-opaque substance, biomolecules, or biostable polymers (page 3, 4th full paragraph; page 8, 1st full paragraph; page 10, last paragraph; page 11, 1st full paragraph). The particles are

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spherical having diameter from about 5 to 20 microns (page 8, 3rd and 4th full paragraphs). The layer containing the particles is covered by polymeric topcoat that helps immobilization of the particles on the surface of the device and controls the release of the therapeutic agents from the surface of the device (page 17, 1st paragraph). The particles deposited on the surface of the device may be made of different substances (page 12, last paragraph).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Although Harish teaches therapeutic particles coated as dry powder on a stent by virtue of adhesive, and further teaches the particles may be made of different substances including biostable and radio-opaque substances, and although the reference teaches combination of therapeutic agents, which implies that inevitable some particles surround others forming pockets, however, the reference does not explicitly teach the therapeutic agent and the microparticles are separate entities as instantly claimed by amended claim 1, or specific material of the particles as being metallic or ceramic as claimed by claim 47.

Alt teaches a stent coated with layer of metal particles having radio-opacity greater than the stent material to provide high visibility of viewing the stent by fluoroscopy during stent deployment in the body. The particles form interstices therebetween that act as repositories for retaining and dispensing therapeutic agents for

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time release therefrom after implantation of the stent. (See the abstract; col.3, lines 45-50; col.7, lines 37-46).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an implantable device coated with dry powdered particles of combination of therapeutic agents, including biomolecules and radio-opaque substances adhered to the surface of the device by primer as taught by Harish, and further add radio-opaque metallic particles to the therapeutic particles of Harish wherein the metallic particles form interstices containing the therapeutic particles therebetween as taught by Alt. One would have been motivated to do so because Alt teaches that metal particles provide high visibility of viewing of the stent by fluoroscopy during stent deployment in the body, and because Alt teaches that the particles form interstices therebetween that act as repositories for retaining and dispensing therapeutic agents for time release therefrom after implantation of the stent. One would reasonably expect formulating an implantable device coated with dry powdered particles of therapeutic agents and metallic radio-opaque particles containing the therapeutic agent therebetween and adhered to the surface of the device wherein the device has high visibility during deployment and timely releases active agents after implantation.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

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instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

7. Applicant's arguments with respect to claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46, 47 have been considered but are moot in view of the new ground(s) of rejection.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611